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## DEVELOPING A FRAMEWORK OF CARE FOR OPIOID MEDICATION MISUSE IN COMMUNITY PHARMACY

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## **Synopsis**

Prescription opioid misuse is a major public health concern, yet few models exist to support engaging community pharmacy patients who misuse opioids. This report describes qualitative results from a meeting of experts aimed at developing a behavioral health framework for opioid medication misuse in the community pharmacy setting. Themes included screening, intervention, prevention, and referral to treatment that capitalize on pharmacists' knowledge of medication management. Interventions should be patient-centered, multidimensional, and multidisciplinary in order to interface with patients at risk or involved in medication misuse.

## Abstract

**Background:** Prescription opioid misuse is a major public health concern in the US. Few resources exist to support community pharmacists engaging patients who misuse or are at risk for misuse.

**Objectives:** This report describes the results of the execution of the ADAPT-ITT model (a model for modifying evidence-based behavioral interventions to new populations and service settings) to guide the development of a behavioral health framework for opioid medication misuse in the community pharmacy setting.

**Methods:** Pharmacy, addiction, intervention, and treatment experts were convened to attend a one-day meeting to review the empirical knowledgebase and discuss adapting the screening, brief intervention, and referral to treatment (*SBIRT*) protocol for addressing opioid medication misuse in community pharmacy. Qualitative data gathered from the meeting were analyzed by 2 independent coders in a 2-cycle process using objective coding schemes. Percentage of agreement and Cohen's Kappa were calculated to assess coder agreement.

**Results:** First-cycle coding identified 4 distinct themes, with coder percentage of agreement ranging from 93.5-99.6% and with Kappa values between 0.81-0.93. Second-cycle coding identified 10 sub-themes, with coder percentage of agreement ranging from 83-99.8% and with Kappa values between 0.58-0.93. Identified themes and sub-themes encompassed patient identification, intervention, prevention, and referral to treatment.

**Conclusions:** Focus of screening efforts in the emerging model should capitalize on pharmacists' knowledge of medication management. Screening likewise should be multidimensional in order to facilitate patient-centered interventions that activate additional disciplines able to interface with patients at risk or involved in medication misuse.

**Keywords:** Opioid misuse, adherence, medication management, qualitative research

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## Introduction

The misuse of prescription opioids has reached epidemic proportions in the US and is a major concern for public health.<sup>1,2</sup> Opioid medication misuse involves diverse behaviors, including taking more medication than prescribed, doctor shopping, early refills, use for psychoactive effects, and/or use to relieve distress besides pain.<sup>3</sup> These behaviors have been documented in clinical settings<sup>3</sup> and health insurance claims.<sup>4</sup> Regular opioid medication consumers who have mental, behavioral, and pain conditions have a heightened-risk for engaging in opioid medication misuse behaviors.<sup>4</sup>

The community pharmacy, a primary location for distribution of opioid medications,<sup>5,6</sup> is one potentially effective location to address misuse. The feasibility of this resource is supported by their ubiquitous presence throughout communities, and pharmacists are one of the most prevalent advanced-degreed health professionals in the nation.<sup>7</sup> Notably, pharmacists are consistently ranked among the most trusted professionals.<sup>8</sup> Furthermore, patients are receptive to receiving behavioral health information from pharmacists,<sup>9</sup> who in turn have positive attitudes and motivation to deliver care to those who misuse opioid medications.<sup>10</sup>

The busy community pharmacy workflow may be especially adaptable to addressing opioid medication misuse by employing the well-established *Screening, Brief Intervention, and Referral to Treatment* (SBIRT) protocol.<sup>11-17</sup> SBIRT integrates screening patients for substance use, with 1 or 2 30 -minute sessions to explore the patient's motivation for change followed, if necessary, by referral to more intensive care. Studies in medical settings have shown that brief interventions can reduce prescription medication misuse, including opioid medication misuse.<sup>18,19</sup> Considering that screening and brief counseling about medications are routine

activities within community pharmacy, the SBIRT protocol could be a valuable yet untapped possibility for addressing misuse of opioid medications.<sup>20</sup>

This potential opportunity is, however, beset by specific challenges, including identification/operationalization of opioid misuse behaviors,<sup>21,22</sup> co-occurring serious health risks such as overdose risk,<sup>23, 24</sup> physical dependence,<sup>25</sup> and legitimate pain management needs.<sup>4, 26-29</sup> Thus, SBIRT models developed for other substances, such as alcohol and tobacco, cannot be simply applied in the community pharmacy setting for addressing opioid medication misuse. Skepticism is reinforced by emerging literature showing that brief motivational interventions for drug use in primary care settings has inconsistent impact on outcomes.<sup>17, 30-32</sup> Accordingly, it is timely to modify SBIRT so as to be congruent with the spectrum and severity of problems associated with opioid medication misuse and its management in the community pharmacy setting.

Toward this goal, this report describes the results of a meeting of an interdisciplinary panel of experts employing ADAPT-ITT (Assessment, Decision, Administration, Production, Topical Experts, Integration, Training, and Testing<sup>33</sup>) to guide modifications of SBIRT for opioid medication misuse in the community pharmacy setting. ADAPT-ITT was designed to serve as a framework for adapting evidence-based HIV interventions. Similar to other initiatives used to modify brief intervention models,<sup>34-37</sup> ADAPT-ITT is a framework for modifying evidence-based behavioral interventions to new populations or service delivery settings.<sup>33</sup> We describe herein results of the utilization of the “ADAPT” portion of the model to modify SBIRT for the community pharmacy setting to address opioid medication misuse. In addition, the results are synthesized into a conceptual framework (Figure 1) that is applicable for integrating patient identification, intervention, prevention, and referral to care for patients in the community

pharmacy setting who are at risk for opioid medication misuse or who are already engaging in this hazardous behavior.

### **Material and Methods**

The Consolidated Criteria for Reporting Qualitative Research (COREQ)<sup>38</sup> was followed to ensure quality and transparency of the methods and results described in this report. COREQ is a checklist consisting of 32 items organized into 3 domains: 1) research team and reflexivity, 2) study design, and 3) analysis and findings. With the exception of items not applicable to our project (interview guides, repeated interviews, and data saturation), the following methods, results, and discussion sections satisfy the COREQ requirements.

### **Attendees**

Eleven experts and 3 practicing pharmacists from the US and UK were invited to participate in a one-day intensive video-recorded meeting held at the University of Pittsburgh to discuss modification of SBIRT for use in community pharmacy to address opioid medication misuse. Attendees were purposively selected and invited based on several criteria, they were: 1) known to the lead author (GC) through collaborative academic/research associations (n=10), 2) identified through a search of the published literature (n=1), and 3) referred from other experts in the field (n=2). Attendants represented expertise in pharmacy, brief intervention, opioid addiction, behavioral interventions, and substance abuse treatment (Table 1). GC was also a participant in the meeting having expertise in brief intervention and addiction. The diverse professional and research backgrounds of the panel members thus enabled obtaining diverse perceptions that could be integrated into a SBIRT model appropriate to the community pharmacy setting.

### **[TABLE 1]**



## Procedures employed in the ADAPT Framework

Prior to convening the experts and again at its beginning, meeting goals were articulated to promote focused discussion and ensure acquisition of accurate comprehensive data. Table 2 lists the 8 ADAPT-ITT components, their procedures, and when each was implemented (or will be implemented in the case of 6, 7, 8, i.e., the “ITT” portion). The first component, *assessment*, consisted of presentations by a subset of attendees focusing on their areas of expertise as it pertains to the goal of the project. Presentation content included brief intervention for drug use in primary care, brief intervention for alcohol use in the community pharmacy setting, brief intervention for medication adherence in the community pharmacy setting, brief intervention for opioid medication misuse in the community pharmacy setting, agonist medication treatment, and naloxone-based opioid overdose prevention. The goal of the presentations was to align the attendees with respect to the empirical knowledgebase relating to prevention, intervention, and treatment of opioid medication misuse in the context of limitations/strengths of modifying the SBIRT model.

The *decision* component, coordinated through a moderator/discussant, involved synthesizing the information contained in the presentations followed by a free-flowing roundtable discussion focusing on identifying novel intervention components as candidates for inclusion in the adapted SBIRT model. The *administration* component, conducted by the presenters, and guided by GC in the question/answer component of the presentations, examined the modifications proposed to adapt SBIRT to the community pharmacy setting. The *production* component, occurring toward the end of and after the meeting, involved GC collecting handwritten notes taken by the attendees, gathering input from other attendees who did not take notes but sent comments via email, and establishing a timeline and agenda to review the video

transcript and notes. Next, in the *topic experts* component of the model, drafts of the results and summary were sent to the attendees for clarification, revision, and comment. The last 3 components; *integration*, *training*, and *testing*; are currently in preparation for a pilot study of the adapted SBIRT model for the community pharmacy setting.

## [TABLE 2]

### **Data Collection and Analysis**

The data consisted of a video recording of the meeting (6 hours), notes from the meeting attendees, and additional notes sent by email. Meeting attendees offered a number of suggestions and comments that were related to opioid misuse, addiction, and pharmacy. The video transcript and meeting notes were analyzed in 2 cycles using a coding process led by GC in which specific content was identified and tallied.<sup>39</sup> This coding and tallying process was facilitated by creating objective coding schemes<sup>40, 41</sup> reflecting the thematic discussion (Table 3). The first cycle coding scheme was developed by GC based on his meeting participation and review of the data. This scheme encompassed 4 themes: patient identification, intervention, prevention, and referral to care. The second cycle coding scheme was developed by GC and a doctoral student research assistant (TY) after completing first cycle coding through reviewing and discussing themes and patterns that emerged from the first cycle. First cycle coding was carried out by GC and TY. Second cycle coding was carried out by TY and a masters -level student research assistant (JR). TY and JR were trained on coding schemes by GC in one-on-one meetings before and during the analysis process in which concepts were reviewed and discussed. Analysis of agreement between coders was conducted using percentage of agreement and Cohen's Kappa (K). K agreement levels of 0.0-0.2 were considered slight, whereas those between 0.21-0.40, 0.41-0.60, 0.61-0.80, >0.80 were respectively considered fair, moderate, substantial, and near/perfect.<sup>42</sup> In addition to

these statistics, selected statements from within the dataset are presented to illustrate the various ideas and themes that emerged. Data were managed, coded, and analyzed using Nvivo 10.<sup>43</sup>

## **Results**

### **First Cycle Codes**

Table 3 displays inter-rater agreement from the first cycle and second cycle coding. As can be seen, patient identification, intervention, prevention, and referral to care, had a high level of agreement ranging from 93.5-99.6% with K values ranging from 0.81-0.93. The most frequent topic identified in the first cycle of coding was intervention (n=296), followed by patient identification (n=206), referral to care (n=67), and prevention (n=19). Results of the first cycle coding were thus deemed informative to be utilized for development of the second cycle coding scheme.

### **[TABLE 3]**

### **Second Cycle Codes**

**Patient identification.** Second cycle coding identified 4 themes that were encompassed in the patient identification code (see Table 3). The first theme focused on defining and operationalizing the target behavior(s) for screening. Although the panelists recognized the importance of screening for a variety of medications and use patterns, the consensus recommendation was to focus screening within the pharmacist area of expertise, namely prescribed opioids with particular emphasis for risk of adverse drug events. With respect to opioid medications, the most important adverse events are misuse, addiction, and overdose.

Inquiring about consumption behavior and adherence to the prescribing regimen can, however, be challenging in the pharmacy setting. In particular, the attendees noted that community pharmacists have a dual role of screening/monitoring and “policing” aberrant

behavior—that is to say—tracking and reporting illegal or suspicious behavior. This dual responsibility is stressful and formally extends the boundaries of professional practice. One participant commented: *“I don’t think the pharmacist... should be in a legal role. Or, they can’t be in both [a helping and a legal role]. It’s going to be hard to be in both, manage both.”*

The discussion within the meeting that could resolve this tension was the central point within the third identified theme. Specifically, electronic surveys in kiosks and/or health record screening to meet busy community pharmacy workflow demands were discussed as tools to lessen the “policing” role of the community pharmacist. Rather than directly interview the patient about opioid use patterns in context of adherence to the prescription regimen, the pharmacist would instead discuss with the patient the results of a health screening. As one participant noted: *“...the pharmacist basically gets data from a person at a kiosk, sits down, and begins with the statement that, ‘this is what you are telling me about yourself. Where do we begin?’ The consultative role of the pharmacist is with the data.”*

In the context of problem identification, the fourth theme thus addressed the need for comprehensive screening. The rationale for a broader health perspective rather than circumscribed focus on drug use behaviors was based on understanding that patients at risk or misusing opioid medications commonly evince a spectrum of problems. Comprehensive screening is therefore a requisite for pharmacists to document the factors predisposing to risk for or sustaining hazardous use of opioid medications.

**Intervention.** Given the complexity of patient behaviors, meeting attendees discussed at length the variety of behaviors that might be targeted for intervention. Although clear consensus was not reached, second cycle coding of the intervention portion of the discussion identified two themes, which from the pharmacist perspective are essential to intervention. First, interventions

must capitalize on the pharmacist's strengths, such as medication review. This task builds on the core competencies of the pharmacists' specific knowledge about medications and their interactions. Moreover, medication review aligns with community pharmacy workflow. One participant asserted: *"...pharmacists [could]... support patient safety with respect to prescription opiate use based upon dose/type/other medications being used/disease status. This could be built from a Comprehensive Medication Review."*

The second theme explored the concept of patient-centered interventions. This discussion examined the importance of asking patients their preferences regarding the focus of any proposed intervention. One participant urged: *"The sessions must be negotiated from a menu of alternatives, which are taken directly from the patient's perception of the problem, or if possible, reframed by the interventionist in a way that is agreeable to patients."*

**Prevention.** The third theme in second cycle coding, *prevention*, identified 2 themes: first, preventing patients from proceeding to addiction, and second, averting overdose. Prevention of overdose was discussed primarily in relation to training pharmacists in naloxone rescue. One participant commented: *"...we talk about prevention of overdose, of saying hey, if you are going to have [opioid] medications available to you; they're going to be in your home; we need to get some ancillary type of medications in your home to reverse an overdose."*

**Referral to treatment.** The referral to treatment discussion also focused on 2 themes. The first was reconnecting patients to prescribers for higher levels of care (e.g., agonist treatment). The second was connecting patients with physical, behavioral, and/or mental health conditions to health professionals. One participant remarked: *"If it's going to get complicated really fast, you're going to want to do something there [that] connects the person to a [health*

care] team that includes...the pharmacist, the primary care clinician, the nurse in the primary care clinician's office, the social worker or behavioral specialist....”

### Discussion

Themes coded in the first and second cycle coding process possessed high levels of inter-rater agreement and K values—thus demonstrating consistency and salience of the topics pertinent to pharmacist-based intervention for opioid medication misuse. Considered in aggregate, the results have several implications for a community pharmacy-based model for opioid medication misuse. Specifically, the components of an integrative framework, shown in Figure 1, underscore the importance of joining drug-specific and medical/psychological screening spanning 4 main levels of severity, ranging from no risk to addiction—thus setting the stage for a practical patient-centered work plan for addressing opioid medication misuse in the community pharmacy setting.

One of the most frequently discussed themes, *patient identification*, emphasized the importance of capitalizing on the pharmacist's expertise, especially promoting adherence to the prescription regimen and preventing adverse drug events. Consuming more medication than prescribed, detecting early refills, and inappropriate use of medications are within the scope of pharmacists' training and expertise. Opioid medication misuse often co-occurs with multiple health problems, which may lie outside pharmacists' competencies. Accordingly, identification of high-risk or medication abusing patients must be comprehensive. Multidimensional information ideally would be captured using electronic methods such as kiosks and/or health record review. Electronic patient identification methods also have the benefit of removing the policing burden from the pharmacist, particularly considering that pharmacists report they believe patients would respond to electronic screening more favorably than face-to-face

methods.<sup>10</sup> Although not a strong theme of this project, attendees did note that comprehensive screening should employ measures that take into account burden of time on both the patient and the pharmacy.

Discussion also explored the role of the pharmacist on intervention. Medication management emphasizing adherence to the prescription regimen and safety are core professional activities that could readily be accommodated into intervention practice.<sup>20</sup> Results from clinical trials demonstrate that pharmacists providing medication management can significantly improve the health behaviors of patients.<sup>44, 45</sup> A recent systematic meta-analysis located 44 medication therapy management (MTM) studies that suggested consistent improvement in behaviors such as medication adherence while lowering health care costs.<sup>44</sup> MTM, consensually accepted in the pharmacy field as helpful to patients,<sup>45</sup> has been codified into standardized guiding principles<sup>46, 47</sup> and is supported by both some commercial insurance products and Medicare.<sup>48</sup> Moreover, substance abuse screening and intervention can be easily incorporated in interventions that pharmacists provide within MTM.<sup>45</sup> Brief “targeted” MTM interventions are also becoming more common and could likewise be implemented to address opioid medication misuse.<sup>49</sup> Altogether, addressing opioid medication misuse by adapting the SBIRT model in the pharmacy setting entails conceptualizing the task as screening, intervening, prevention, and referring (if necessary) to manage medications so as to improve adherence and safety.

A patient-centered approach to intervention emphasizes the unique circumstances of each patient. Whereas the community pharmacy may be a readily accessible starting point for intervention, many factors beyond pharmacists’ scope of practice spanning addiction, medical problems, social adjustment, and family problems may also be undergirding hazardous use of opioid medications. Consequently, the pharmacist needs to be included within a team-based

model of patient care that includes physicians, nurses, physical/occupational therapists, and social workers/behavioral health providers. A team-based approach to health care is an emerging model that is currently at varying levels of adoption within the larger health care environment. The new idea suggested in this project is that the community pharmacy should be included as an entry point of patient engagement.

### **Limitations**

Several limitations of this study should be noted. The attendees represented a variety of training and practice backgrounds that, although producing rich discussion, may have under-emphasized the importance of the pharmacist's perspective. These rich discussions therefore did not allow for the group to come to a clear consensus regarding details of a pharmacy-based intervention for opioid misuse. However, a clear framework arose as a guide to future delineation of a specific intervention protocol. Furthermore, the attendees in the *Topical Experts* portion of the ADAPT-ITT process were not required to review the entirety of the data in their assessment of these results. Rather, the attendees were asked to review only the results presented herein. All files were made available to attendees for their review if they wished to examine raw data. However, given the high level of agreement between the coders, the schemes and the data are considered to be accurate representations of the discussion.

### **Conclusion**

A one-day intensive meeting was convened to review the empirical knowledgebase and discuss adapting the SBIRT protocol for opioid medication misuse in the community pharmacy setting. Discussions explored patient identification, including comprehensive assessment using electronic methods to fit within community pharmacy workflow and to avoid involving the pharmacist in a policing role. Adaptation of SBIRT for community pharmacy concentrated on



capitalizing on the pharmacist's knowledge of medication management, particularly related to adverse events and medication adherence. However, patients who misuse opioid medication often have problems that exceed the core competencies of the pharmacist. Interventions for acute needs should be team-based and encompass the range of disciplines that interface with medication misuse. Furthermore, a patient-centered intervention model is recommended whereby the factors that uniquely contribute to individual onset and maintenance of opioid misuse are taken into account.

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**Table 1. Expertise of attendees (n)**

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Opioid overdose prevention and harm reduction expert (1)

Health services pharmacy expert (1)

Pharmacologic opioid treatment expert (1)

Practicing addiction pharmacist (1)

Psychosocial addiction treatment expert (1)

Practicing community pharmacists (2)

Behavioral intervention experts (3)

Brief intervention and addiction experts (4)

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**Table 2. ADAPT-ITT framework for modifying SBIRT in the community pharmacy setting for opioid medication misuse**

<b>Model Component</b>	<b>Objective</b>	<b>Executed</b>
1. Assessment	Presentations by attendees	Scientific working session
2. Decision	Discussant summarization and roundtable discussion of needed intervention components	Scientific working session
3 Administration	Topic specific discussion on needed changes to screening, intervention, prevention, and referral to treatment	Scientific working session
4. Production	Gather written notes	Scientific working session/post scientific working session
	Plan review of video recordings	
	Plan writing up meeting proceedings and adapted SBIRT model	
	Analyzing and writing up meeting results	Post scientific working session
5. Topic Experts	Sending results to meeting attendees for review	Post scientific working session
	Revising manuscript based on feedback	
6. Integration	Incorporate SBIRT model into research protocol	Post scientific working session
7. Training	Training approach/methods in research protocol	Post scientific working session
8. Testing	Pilot study methodology in research protocol	Post scientific working session

**Table 3. Coding schemes and inter-rater agreement**

First cycle codes	Second cycle codes	% Agreement	Kappa	Total n of codes
Patient identification		97.3	0.88	206
	Operationalize target behavior	93.7	0.63	66
	Policing role	99.8	0.84	12
	Use EHR or electronic screen	99.5	0.78	9
	Comprehensive assessment	96.9	0.63	40
Intervention		93.5	0.81	296
	Building on pharmacy strengths	87.6	0.60	67
	Patient-centered intervention	83.0	0.58	52
Prevention		99.6	0.92	19
	Prevention of SUD	99.7	0.91	23
	Overdose prevention	97.3	0.84	20
Referral to care		99.5	0.93	67
	Refer to professionals to assist in follow through	99.1	0.63	21
	Refer back to prescribers for additional care	99.8	0.86	14

**Figure 1. Targeted intervention framework within community pharmacy workflow**

